UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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KING PHARMACEUTICALS, INC., et al.,

Plaintiffs/Counterclaim Defendants,

-against-

EON LABS, INC.,

Defendant/Counterclaim Plaintiff,

-against-

ELAN PHARMACEUTICALS, INC.,

Counterclaim Defendant.

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MEMORANDUM AND ORDER

04-CV-5540 (DGT)

ROANNE L. MANN, UNITED STATES MAGISTRATE JUDGE:

Currently pending before this Court, on a referral from the Honorable David G. Trager, is a motion filed by defendant/counterclaim plaintiff Eon Labs, Inc. ("Eon") to eliminate the confidentiality designation of briefs submitted in support of and opposition to Eon's Motion for Determination of Exceptional Case. See Letter to Judge Trager Regarding Dispute (June 2, 2009) ("Eon 6/2/09 Letter"), ECF Docket Entry ("D.E.") #313; [Referral] Order (Jan. 14, 2010) ("1/14/10 Order"), D.E. #347. The unsealing motion is opposed by plaintiffs/counterclaim defendants King Pharmaceuticals, Inc. and King Pharmaceuticals Research and Development, Inc. (collectively, "King") and by counterclaim defendant Elan Pharmaceuticals, Inc. ("Elan"). See Letter Response to Eon's Letter (June 5, 2009) ("King 6/5/09 Letter"), D.E. #315; Letter [from] Kevin J. McKenna to Judge Trager (June 5, 2009) ("Elan 6/5/09 Letter"), D.E. #316; see also Letter Addressing the King Letter and Elan Letter

(June 10, 2009) ("Eon 6/10/09 Reply"), D.E. #318. For the reasons that follow, Eon's motion to unseal is granted in its entirety.

FACTUAL BACKGROUND

King sued Eon for infringement of U.S. Patents Nos. 6,407,128 ("'128 patent") and 6,683,102 ("'102 patent"), which disclose methods of increasing the bioavailability of metaxalone (marketed by King as "Skelaxin®") by administering the drug with food. Elan is King's predecessor -- King purchased the '128 patent from Elan and then filed a continuation patent application, which resulted in the issuance of the '102 patent. On January 20, 2009, in response to a summary judgment motion filed by Eon, Judge Trager issued a Memorandum and Opinion declaring those patents invalid as a matter of law. See Memorandum and Order (Jan. 20, 2009) at 32, D.E. #290, reported at 593 F.Supp.2d 501.[1] Thereafter, Eon filed its Motion for Determination of Exceptional Case. See Notice of Motion for Attorney Fees and Determination of Exceptional Case, D.E. #305. Judge Trager denied the motion for fees on September 28, 2010. See Memorandum and Order (Sept. 28, 2010) ("9/28/10 M&O"), D.E. #356. The issue before this Court is whether the briefing in support of and opposition to that motion should remain under seal.[2]

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[1] On August 2, 2010, the Federal Circuit affirmed in part and vacated in part Judge Trager's decision. See King Pharms., Inc. v. Eon Labs, Inc., -- F.3d --, 2010 WL 300133 (Fed. Cir. Aug. 2, 2010). The Court of Appeals agreed that both patents are invalid, but concluded that the district court lacked subject matter jurisdiction to adjudicate the invalidity counterclaim against Elan, because no case or controversy currently exists between Elan and Eon; the invalidity order against Elan was therefore vacated. See id. at *14-15.

[2] The briefing at issue consists of the following submissions: Eon's Memorandum of Law in (continued…)

The confidentiality designations at issue were made pursuant to a stipulated protective order that allowed the producing party to designate any material as confidential, without a showing of good cause, based on a good faith belief in the need for confidential treatment. See Amended Protective Order ("Stipulation") ¶ 2, D.E. #19.[3] The agreed-upon document further provided that

> [i]n the event that any party disagrees at any stage of the proceedings with such [a confidentiality] designation, such party shall . . . first try to dispose of such dispute in good faith on an informal basis. If the dispute cannot be resolved within ten days of the challenging party's written notice, the party challenging the designation may then request appropriate relief from this Court. The burden of proving the information has been properly designated . . . is on the Producing Party making such designation.

See Stipulation ¶ 10.

After informal attempts failed to resolve the instant dispute within ten days, Eon requested relief from Judge Trager. See Eon 6/2/09 Letter at 2, D.E. #313. Both King and Elan submitted responsive letters opposing the unsealing of the briefs, and Eon replied to those objections. See King 6/5/09 Letter; Elan 6/5/09 Letter; Eon 6/10/09 Reply. King then

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[2](…continued)
Support of Eon's Motion for Determination of Exceptional Case ("Eon Brief"), D.E. #306; Plaintiffs King Pharmaceuticals, Inc. and King Pharmaceuticals Research and Development, Inc.'s Opposition to Eon Labs, Inc.'s Motion for Determination of Exceptional Case ("King Brief"), D.E. #348; Elan Pharmaceuticals, Inc.'s Response in Opposition to Motion for Attorney Fees ("Elan Brief"), D.E. #310; Eon's Reply Memorandum In Support of Its Motion for Determination of Exceptional Case (July 6, 2009) ("Eon Reply Brief"), D.E. #332.

[3] Although entitled a "protective order" by the parties, the stipulation is not, strictly speaking, a protective order issued by the Court on a finding of good cause, within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure. See generally *infra* p. 6-7. Therefore, the document is cited herein as "Stipulation."

submitted redacted briefs, with Elan's acquiescence, see Letter Proposing Redacted Briefing (June 15, 2009) ("King 6/15/09 Letter"), D.E. #320; Letter to Judge Trager (June 15, 2009) ("Elan 6/15/09 Letter"), D.E. #321; and Eon's counsel requested that those redacted briefs be made available to his clients. See Motion to Unseal Document (June 17, 2009) ("Eon 6/17/09 Letter"), D.E. #322.

On June 25, 2009, Judge Trager issued a Memorandum and Order requiring King and Elan to submit letters identifying "each piece of allegedly confidential information contained in the unredacted briefs," with "detailed reasons why each piece of information should remain sealed." Memorandum and Order (June 25, 2009) ("6/25/09 M&O") at 2, D.E. #324 (emphasis in original). Judge Trager further ordered that King and Elan identify confidential information belonging to third parties, and that "any third parties wishing to submit a letter regarding their allegedly confidential information shall do so within 14 days . . . ." Id. at 3. The Court reminded the parties that "the burden is on the party producing allegedly confidential information to show that it[']s properly designated as confidential if that designation is challenged," and concluded that "Eon has adequately identified the information it believes has been improperly designated as confidential." Id. at 2 (citing Stipulation ¶ 10). Thereafter, Elan, King, and non-party Mutual Pharmaceutical Company, Inc. ("Mutual") each filed letters identifying those portions of the briefing that they believed should remain redacted and under seal. See Letter Motion for Protective Order (July 9, 2009) ("Elan 7/9/09 Letter"), D.E. #333; Sealed Letter to Judge Trager (July 9, 2009) ("King 7/9/09 Letter"), D.E. #334; Letter Dated 7.10.09 By Mutual Pharmaceutical Company, Inc. (July 10, 2009) ("Mutual

7/10/09 Letter"), D.E. #335.[4]

On January 14, 2010, Judge Trager issued a referral order, pursuant to which the undersigned magistrate judge is to determine "[t]he issue of whether the unredacted briefs in this case contain any confidential information of the counterclaim defendants or any third parties, such that they should remain sealed." 1/14/10 Order. For the reasons that follow, this Court orders that the briefs be unsealed in their entirety, as they contain no confidential information warranting sealing and/or redaction.

APPLICABLE LEGAL PRINCIPLES

I. Reliance on a Stipulated Protective Order

Rule 26(c) of the Federal Rules of Civil Procedure governs a court's power to issue an order "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." Fed. R. Civ. P. 26(c)(1). "The touchstone of the court's power under Rule 26(c) is the requirement of 'good cause.'" In re Zyprexa Injunction, 474 F.Supp.2d 385, 415 (E.D.N.Y. 2007); see also Fed. R. Civ. P. 5.2(e)(1) ("For good cause, the court may by order in a case . . . require redaction" of information other than social security numbers and other data expressly protected under Rule 5.2(a)). To establish good cause, a party must demonstrate that "a 'clearly defined and serious injury' . . . would result from disclosure of the document." Allen v. City of New York, 420 F.Supp.2d 295, 302 (S.D.N.Y. 2006) (citations omitted); J. Moore, 6 Moore's Federal Practice & Procedure § 26.104[1], at 510-12 (3d ed. 2009).

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[4] No requests to redact the Eon Reply Brief have been made.

In this case, King and Elan argue, among other things, that the challenged redactions should be maintained because third parties relied in good faith on the Court's issuance of a protective order. See King 7/9/09 Letter at 2-3; Elan 7/9/09 Letter at 4-5. Although reasonable reliance on a previously granted protective order may create a presumption against disclosure, see Martindell v. Int'l Tel. & Tel. Corp., 594 F.2d 291, 296 (2d Cir. 1979), the law is clear that the *Martindell* presumption against disclosure does not apply where, as here, confidentiality designations are made without a showing of good cause. See Schiller v. City of New York, No. 04 Civ. 7922 KMK JCF, 2007 WL 136149, at *3 (S.D.N.Y. Jan. 19, 2007) ("Where a protective order permits parties to designate discovery materials as 'Confidential' without a showing of good cause, and one party challenges a designation made by another, the challenging party is not seeking to modify the protective order and therefore does not bear the burden of demonstrating that the confidentiality designations should be lifted.").

Moreover, the *Martindell* presumption applies only to those materials produced "under a protective order when there was reasonable reliance upon such an order . . . ." S.E.C. v. TheStreet.com, 273 F.3d 222, 231 (2d Cir. 2001). Here, however, the order on which the non-parties are alleged to have relied expressly provided a mechanism for challenges to confidentiality designations. See Stipulation ¶ 10. As a consequence, any reliance on that order "is insufficient to outweigh the strong presumption in favor of public access" to court records. Diversified Group, Inc. v. Daugerdas, 217 F.R.D. 152, 160 (S.D.N.Y. 2003); accord Gambale v. Deutsche Bank AG, 377 F.3d 133, 142 n.7 (2d Cir. 2004) ("[P]rotective orders that are on their face temporary or limited [do] not justify reliance by the parties.")

(quoting TheStreet.com, 273 F.3d at 231); Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 126 (2d Cir. 2006); Allen, 420 F.Supp.2d at 301. In other words, because the confidentiality designations in this case were made without a showing of good cause, the Court affords no weight to the previous grant of what King and Elan characterize as a protective order. Rather, the burden remains on the party resisting disclosure to demonstrate good cause for maintaining confidentiality, pursuant to Rules 26(c) and 5.2(e). See U2 Home Entm't, Inc. v. Kylin TV, Inc., No. 06-CV-2770 (DLI), 2008 WL 1771913, at *2 (E.D.N.Y. Apr. 15, 2008) (where "the confidentiality designation is contested, the party seeking to maintain confidential treatment for the challenged document will have the burden of establishing good cause for the continuation of that treatment") (quoting Lachica v. City of New York, 94-CV-7379 (LAK), 1995 WL 77928, at *1 (S.D.N.Y. Feb. 23, 1995)). Because "the document[s] sought to be shielded from disclosure [are] part of the official court file, the Court must consider the public's presumptive right of access to such materials in making its determination as to good cause." Nycomed U.S., Inc. v. Glenmark Generics, Inc., No. 08-CV-5023 (CBA), 2010 WL 889799, at *2 (E.D.N.Y. Mar. 8, 2010).

II. The Presumptive Right of Public Access

"The courts have long recognized a common law right of public access to judicial documents." Stern v. Cosby, 529 F.Supp.2d 417, 420 (S.D.N.Y. 2007) (quotations and citations omitted); see, e.g., Lugosch, 435 F.3d at 119. The public's "right to inspect and copy . . . judicial records and documents," Nixon v. Warner Commc'ns, Inc., 435 U.S. 589,

597 (1978), is "founded upon the public's interest in monitoring the judiciary's administration of justice." United States v. Basciano, Nos. 03-CR-929, 05-CR-060, 2010 WL 1685810, at *2 (E.D.N.Y. Apr. 23, 2010) (citing United States v. Amodeo, 71 F.3d 1044, 1048 (2d Cir. 1995) ("Amodeo II")). As the Second Circuit explained:

> Transparency is pivotal to public perception of the judiciary's legitimacy and independence. The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat and requires rigorous justification.

United States v. Aref, 533 F.3d 72, 83 (2d Cir. 2008) (quotation and citation omitted).

Nevertheless, the common law right to inspect and copy judicial documents is a qualified right, not an absolute one. See Nixon, 435 U.S. at 598; accord United States v. Graham, 257 F.3d 143, 149 (2d Cir. 2001). The right of public access gives rise to a rebuttable presumption of public availability, the weight of which presumption "must be governed by the role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts." Amodeo II, 71 F.3d at 1049. In applying this presumption, "'a judge must carefully and skeptically review sealing requests to insure that there really is an extraordinary circumstance or compelling need' for the request." Mariano v. La Fitness, Inc., No. CV 09-1395(LDW)(ETB), 2010 WL 1459383, at *1 (E.D.N.Y. Apr. 13, 2010) (quoting Video Software Dealers Ass'n v. Orion Pictures Corp., 21 F.3d 24, 27 (2d Cir. 1994)).[5]

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[5] The Second Circuit has also recognized a qualified constitutional presumption of access to both civil and criminal proceedings and judicial documents, arising under the First

(continued…)

"The Second Circuit has set forth a three-part analysis for determining whether documents relating to a lawsuit must be made available to the public." Stern, 529 F.Supp.2d at 420 (citing Lugosch, 435 F.3d at 119-20; Amodeo II, 71 F.3d at 1048-52).

> First, the court must determine whether the documents are indeed judicial documents, to which the public has a presumptive right of access. Second, if the documents are judicial documents, the court must determine the weight of the presumption, that is, whether the presumption is an especially strong one that can be overcome only by extraordinary circumstances or whether the presumption is a low one that amounts to little more than a prediction of public access absent a countervailing reason[,] or whether the presumption is somewhere in between. Third, once the weight of the presumption is determined, a court must balance competing considerations against it. Countervailing factors include, among others, the danger of impairing judicial efficiency and the privacy interests of those resisting disclosure.

Stern, 529 F.Supp.2d at 420 (internal quotations and citations omitted); accord Nycomed, 2010 WL 889799, at *2; Diversified Group, 217 F.R.D. at 158-60.

Regarding the first step (whether the presumption of access applies), "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, become documents to which the presumption of public access applies." Lugosch, 435 F.3d at 122 (quotations and citations omitted). The documents

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[5](…continued)
Amendment. See Nycomed, 2010 WL 889799, at *3 (citing Lugosch, 435 F.3d at 124; Gambale, 377 F.3d at 140 & n.4). Because this Court concludes that the common law right of access mandates disclosure of the briefs in question, it need not determine whether they are also subject to a First Amendment presumption of access, which "demands broader disclosure than the common law." In re NBC Universal, Inc., 426 F.Supp.2d 49, 56 (E.D.N.Y. 2006) (emphasis omitted) (citing Lugosch, 435 F.3d at 124); see generally Basciano, 2010 WL 1685810, at *2 n.3 (where common law right of access required public disclosure, court declined to reach constitutional question of access).

that Eon seeks to unseal are briefs submitted in support of or opposition to its motion for determination of exceptional case. As such they clearly constitute "judicial documents."

Regarding the second step in the analysis, the weight of the presumption of public access depends on the

> role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts. Generally, the information will fall somewhere on a continuum from matters that directly affect an adjudication to matters that come within a court's purview solely to insure their irrelevance.

Amodeo II, 71 F.3d at 1049. Legal briefs "used by parties moving for, or opposing" a dispositive motion fall on the far end of the continuum and are subject to the strongest presumption. Lugosch, 435 F.3d at 123; see Gambale, 377 F.3d 140 ("the presumptive right to 'public observation' is at its apogee when asserted with respect to documents relating to 'matters that directly affect an adjudication.'"); Joy v. North, 692 F.2d 880, 893 (2d Cir. 1982) ("documents used by parties moving for, or opposing, summary judgment should not remain under seal absent the most compelling reasons"); Stern, 529 F.Supp.2d at 422 (reasoning that the strength of the presumption turns on whether the submissions were made in support of a motion on the merits); Diversified Group, 217 F.R.D. at 158-59 ("The presumption is given great weight where the requested documents were . . . material to a court's disposition of a case on the merits.").

Here, the disputed documents are submissions supporting or opposing Eon's motion for

a determination of exceptional case, pursuant to 35 U.S.C. § 285.[6] As liability has already been determined, that motion does not, strictly speaking, go to the ultimate merits of the case. Nevertheless, the briefing in question concerns a substantive adjudication that will determine liability for attorneys' fees, which are often quite significant in patent infringement cases. Where, as here, the judicial documents "play a substantial role 'in determining litigants' substantive rights,'" In re Zyprexa Injunction, 474 F.Supp.2d at 412 (quoting Amodeo II, 71 F.3d at 1049), "[t]he claim of public access is strongest . . . ." Id. Consequently, the disputed documents fall on the far end of the continuum, such that they at least are subject to a strong presumption of access, if not the strongest.

III. Factors Cited In Opposition To Public Disclosure

The Court now addresses the legal standards governing the countervailing factors that King and Elan proffer to rebut the strong presumption of public access.[7]

A. Confidential Business Information/Trade Secrets

In opposing the unsealing of redacted portions of the briefs, Elan and King complain that such disclosure would compromise their business and competitive standing by revealing "highly sensitive proprietary and trade secret information . . . ." Elan 7/9/09 Letter at 2; see id. at 2-3; see also King 7/9/09 Letter at 1-2; King 6/5/09 Letter at 2. In effect, they seek a

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[6] Section 285 provides: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285.

[7] King turns this inquiry on its head, and thus applies an erroneous legal standard, in arguing that "there is no compelling reason to destroy the confidentiality of [] King's documents." King 6/5/09 Letter at 2; see also id. at 3 (arguing the lack of "a compelling need" to obtain access to King's "confidential information").

protective order under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, which provides that, for good cause shown, a court may "requir[e] that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way . . . ."[8] Fed. R. Civ. P. 26(c)(1)(G). Because the business information in question is contained in judicial documents, the "party seeking to preclude disclosure of trade secrets has the burden to show that the information in fact constitutes a trade secret, that disclosure would harm movant's competitive position and that the asserted harm outweighs the presumption of public access." Encyclopedia Brown Prods., Ltd. v. Home Box Office, Inc., 26 F.Supp.2d 606, 613 (S.D.N.Y. 1998); accord Nycomed, 2010 WL 889799, at *5; see also Cuno Inc. v. Pall Corp., 117 F.R.D. 506, 507-08 (E.D.N.Y. 1987) (the party seeking protection for alleged trade secrets bears the burden of demonstrating good cause for such a classification) (collecting cases).

In recently resolving a similar dispute over redactions in a pharmaceutical patent case, this Court summarized the legal principles applicable to requests to seal purported trade secrets and confidential business information:

> To assess whether information constitutes a trade secret, courts in this circuit have looked to the Restatement of Torts, which defines a trade secret as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Softel, Inc., v. Dragon Med. & Scientific Commc'ns, 118 F.3d 955, 968 (2d Cir. 1997) (quoting RESTATEMENT OF TORTS § 757 cmt. b at 5 (1939)). "[I]mplicit in the notion of 'confidential business

[8] For ease of reference, unless otherwise noted, this Court will use the terms "trade secret" and "confidential business information" interchangeably.

> information' is something beyond the mere fact that the particular datum has not previously been made available to the public." Salomon Smith Barney, Inc. v. HBO & Co., 98 Civ. 8721(LAK), 2001 WL 225040, at *3 (S.D.N.Y. Mar. 7, 2001). "In determining whether information warrants protection as a [Rule 26(c)] trade secret, courts have considered the following: (1) the extent to which the information is known outside the business; (2) the extent to which it is known by employees and others involved in the business; (3) the measures taken to guard the information's secrecy; (4) the value of the information to the business or to its competitors; (5) the amount of time, money, and effort expended in development of the information; and (6) the ease or difficulty [in] duplicating or properly acquiring the information." Chembio Diagnostic Sys., Inc. v. Saliva Diagnostic Sys., 236 F.R.D. 129, 136 (E.D.N.Y. 2006).

Nycomed, 2010 WL 889799, at *5 (alterations in original); see also U2 Home Entm't, 2008 WL 1771913, at *2.

In other words, an assertion of confidential business information, without more, will not merit trade secret protection. See Nycomed, 2010 WL 889799, at *5. "[C]onclusory statements are insufficient to satisfy the burden of showing good cause." Cuno, 117 F.R.D. at 508. Rather, "[t]he party opposing disclosure must make a particular and specific demonstration of fact showing that disclosure would result in an injury sufficiently serious to warrant protection; broad allegations of harm unsubstantiated by specific examples or articulated reasoning fail to satisfy the test." In re Parmalat Secs. Litig., 258 F.R.D. 236, 244 (S.D.N.Y. 2009) (collecting cases); see Encyclopedia Brown, 26 F.Supp.2d at 613 ("With respect to proof of competitive harm, vague and conclusory allegations will not suffice. Movant must prove that disclosure would work a clearly defined and very serious injury.") (internal quotations and citations omitted).

B. Confidential Communications with the Food and Drug Administration ("FDA")

In support of their respective pleas for nondisclosure, King and Elan each assert that "[c]ommunications between drug approval applicants and the FDA are confidential." King 7/9/09 Letter at 1; see King 6/5/09 Letter at 2; Elan 7/9/09 Letter at 2. This argument misconstrues the cited FDA regulation and related caselaw, and was rejected by this Court in circumstances indistinguishable from the case at bar. See Nycomed, 2010 WL 889799, at *4-5.

The regulation relied upon, to wit, 21 C.F.R. § 314.430(b)-(d), does not guarantee that communications with the FDA concerning a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") (collectively, "applications") will remain shielded from disclosure *after* the application is approved by the FDA. As an initial matter, the regulation, by its terms, applies only to information concerning pending or unapproved applications,[9] and

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[9] The cited subsections read as follows:

> (b) FDA will not publicly disclose the existence of an application or abbreviated application *before an approval letter is sent to the applicant* under § 314.107, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged.
>
> (c) If the existence of an *unapproved application* or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.
>
> (d)(1) If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure *before the agency sends an approval letter*,

(continued…)

not to information concerning applications that the FDA has approved. See Cunningham v. Smithkline Beecham, No. 2:07 CV 174, 2008 WL 2572076, at *4 (N.D. Ind. June 25, 2008). Indeed, "[a]fter [the] FDA sends an approval letter to the applicant," summary data, including "all correspondence and written summaries of oral discussions between FDA and the applicant," are made "immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist." 21 C.F.R. § 314.430(e); see Cunningham, 2008 WL 2572076, at *4. Only bona fide trade secrets or confidential commercial or financial information are exempted. See 21 C.F.R. §§ 20.60, 20.61, 314.430(g). Furthermore, even prior to approval, the "regulation governs disclosures by the FDA and does not prohibit disclosure by a third party, or the applicant." Nycomed, 2010 WL 889799, at *4 (citing 21 C.F.R. § 314.430(b)).

Contrary to the implications of Elan and King's argument,[10] judicial precedent does not afford blanket protection against disclosure of communications with the FDA. Instead, each case turns on its particular facts, and a court will order sealing only where the party resisting disclosure has made a particularized showing of harm that would result from revealing trade secrets. Compare In re Gabapentin Litig., 312 F.Supp.2d 653, 667-68 & n.7 (D.N.J. 2004)

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[9](…continued)

> but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee.

21 C.F.R. § 314.430(b)-(d) (emphasis added).

[10] See King 7/9/09 Letter at 1-2; King 6/5/09 Letter at 2; Elan 7/9/09 Letter at 2.

(where parties' assertions of trade secret protection were supported by sworn certifications and declarations, and the communications in question included "secret chemical formulas [and] the parties' suppliers," the court concluded that the parties had made "a particularized showing of the need for continued secrecy sufficient to overcome the presumption of access"); Biovail Labs., Inc. v. Anchen Pharms., Inc., 463 F.Supp.2d 1073, 1083-84 (D.N.J. 2006) (declining to modify protective order to allow additional attorneys and consultants for plaintiff to review defendant's *pending* ANDA and amendments thereto, where it was "indisputable" that those documents contained "trade secrets, the disclosure of which to a competitor such as [plaintiff] (or the public) would be extremely damaging to [defendant's] interests"), with Forst v. Smithkline Beecham Corp., 639 F.Supp.2d 948, 957 (E.D.Wis. 2009) (granting plaintiffs' motion to unseal where defendant failed to "establish good cause for sealing either its correspondence with the FDA, or for sealing related deposition testimony"); Cunningham, 2008 WL 2572076, at *3-5 (granting plaintiffs' request to unseal NDA documents submitted by defendant to the FDA, and deposition testimony concerning the contents thereof, where defendant failed to show that the materials contained trade secrets); Contratto v. Ethicon, Inc., 227 F.R.D. 304, 309-12 (N.D. Cal. 2005) (rejecting defendants' confidentiality designations for materials, including communications with the FDA, because defendants failed to identify any "specific secret or otherwise show the specific harm that will result from disclosure of each document"); Waelde v. Merck, Sharp & Dohme, 94 F.R.D. 27, 29 (E.D. Mich. 1981) (rejecting drug manufacturer's application for a protective order against disclosure of information in NDA, on the ground that "to be completely exempt from disclosure . . . , the

contents of a NDA file must be a trade secret or confidential information as well as not previously publicly disclosed").

Simply put, the communication of information to the FDA in connection with a drug application does not automatically trigger protection against disclosure. Accordingly, to satisfy their burden of good cause pursuant to Rule 26(c), Elan and King must demonstrate that disclosure of particular information communicated to the FDA would result in a clearly defined and serious injury, and that the asserted harm outweighs the strong common law presumption of public access to the parties' briefs. See Nycomed, 2010 WL 889799, at *5.

C. Third-Party Interests

Privacy interests of non-parties resisting disclosure may weigh heavily against public access to the information at issue. See Amodeo II, 71 F.3d at 1050-51 (citing Gardner v. Newsday, Inc. (In re Newsday, Inc.), 895 F.2d 74, 79-80 (2d Cir. 1990)). Among other things, courts should consider the extent to which the subject matter of the material in question is traditionally considered private rather than public. See Amodeo II, 71 F.3d at 1051; accord TheStreet.com, 273 F.3d at 232. Likewise pertinent to a court's determination are the sensitivity of the information and the nature and degree of injury likely to result from granting public access. See Amodeo II, 71 F.3d at 1051. In short:

> Among the factors for a court to consider in evaluating the privacy interest of those opposing disclosure are the following: (1) the privacy interests of "innocent third parties," which constitute a "venerable common law exception to the presumption of access"; (2) "the degree to which the subject matter is traditionally considered private rather than public," a determination in which "family affairs, illnesses, embarrassing conduct with no public ramifications, and similar matters will weigh more heavily against access than conduct affecting a substantial portion

> of the public"; and (3) "the nature and degree of the injury" that will be caused by revealing the information, which may include determining "whether the nature of the materials is such that there is a fair opportunity for the subject to respond to any accusations therein."

Roberts v. Lederman, No. 04-CV-00033 (NGG), 2004 WL 2238564, at *7 (E.D.N.Y. Oct. 4, 2004) (quoting Amodeo II, 71 F.3d at 1050-51). "A 'generalized concern of adverse publicity' is not, however, a sufficiently compelling reason to outweigh the presumption of access." Nycomed, 2010 WL 889799, at *8 (quoting Prescient Acquisition Group, Inc. v. MJ Publ'g Trust, 487 F.Supp.2d 374, 376 (S.D.N.Y. 2007)). Rather, the individual or entity seeking to maintain redactions must make a sufficient showing of good cause to justify the sealing of portions of judicial documents. See id. (citing Doe v. Greiner, 662 F.Supp.2d 355, 363 (S.D.N.Y. 2009)).

APPLICATION OF THE LAW TO THE FACTS OF THIS CASE

I. Portions that Elan Seeks to Redact

According to Elan, the information that it seeks to maintain as confidential falls into the following five categories: (1) confidential communications to the FDA regarding proprietary data related to research and development of Skelaxin; (2) confidential business information regarding the development of Skelaxin; (3) non-public documents that include confidential business and marketing information regarding Skelaxin; (4) confidential research information regarding the development of Skelaxin; and (5) non-public documents that include confidential information of a technical nature regarding Skelaxin. See Elan 7/9/09 Letter at 1. The listed categories do not, however, accurately describe the contents of the excerpts cited by Elan,

which reveal no proprietary data or confidential business information. Elan has failed to sustain its burden to justify nondisclosure of any portions of the briefs.

A. Communications with the FDA

The first category of information identified by Elan consists of Elan's communications with the FDA concerning Skelaxin. For the reasons detailed earlier, such communications are not presumptively confidential.[11] On the contrary, it is Elan's burden to establish, through competent evidence, that those excerpts reveal trade secrets or other confidential business information, the disclosure of which would cause Elan clearly defined and serious harm. See Contratto, 227 F.R.D. at 311 (rejecting defendants' claim of confidentiality where "defendants have not submitted any evidence, in the form of either a declaration or affidavit, demonstrating that this information is proprietary or could otherwise cause them harm."). Elan's perfunctory (and unsworn) characterization of this information as comprising trade secrets in no way satisfies its burden. See Elan 7/9/09 Letter at 2 ("[I]f Elan's trade secrets regarding the particulars of how Elan conducted its studies, formulated, and developed Skelaxin® were to become public knowledge, any of Elan's pharmaceutical competitors could take advantage of this proprietary data, to the detriment of Elan's business and economic interests."); see also Cunningham, 2008 WL 2572076, at *4 (rejecting, as inadequate, "generalized allegations" that "[t]his confidential information must be held from [defendant's] competitors to prevent them from obtaining a competitive advantage").

Furthermore, the Court's examination of the excerpts in question reveals none of the

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[11] See *supra* pp. 14-17.

"proprietary data" or "particulars" to which Elan refers. Elan first seeks to redact references to its communications with the FDA regarding a bioequivalence study. See Elan 7/9/09 Letter at 2; Eon Brief at 4 n.7; Elan Brief at 5 (lines 5-17), 6 (lines 6-14), 11 (lines 14-16). These same communications with the FDA were, however, discussed and summarized in Judge Trager's publicly filed (and published) ruling on Eon's motion for summary judgment. See King, 593 F.Supp.2d at 504. Apparently recognizing that a judicial opinion or adjudication should, "absent exceptional circumstances, be subject to public scrutiny," Joy, 692 F.2d at 893, Elan has never sought to redact that opinion. Thus, the information that Elan would shield from public scrutiny is already a matter of public record and cannot be deemed a protectable trade secret or confidential business information. See Nycomed, 2010 WL 889799, at *6 (rejecting defendant's "conclusory assertion of confidentiality" where "[t]he existence of the ANDA and [defendant's] bioequivalence study are facts already disclosed in this lawsuit"); Contratto, 227 F.R.D. at 311 (rejecting confidentiality designation for formulas that "merely reveal that [certain] tests were done . . . , a fact which is generally discussed in a public document"). Accordingly, Elan's request for these redactions is denied.

Elan also seeks to redact lines 1-5 from page 13 of Eon's brief, referencing the contents of Skelaxin advertising publications that were forwarded to the FDA; those materials in turn discussed prior art publications reporting the half-life of metaxalone. See Elan 7/9/09 Letter at 2. Significantly, the contents of the prior art publications are disclosed in an unredacted portion of the same page of Eon's brief.[12] See Eon Brief at 13 (lines 12-14); Nycomed, 2010

[12] That the redacted portion notes that this information was contained in advertising materials (continued…)

WL 889799, at *6 (refusing to sustain redaction of a portion of an application to the court where the facts recited therein were "already disclosed . . . in unredacted portions of that same letter motion"). Moreover, information contained in published advertisements is already public and cannot constitute confidential business information. Accordingly, this request for redaction is denied.

Elan also seeks to redact a portion of the King Brief, i.e., an excerpt from page 23 (line 24) to page 24 (line 9). See Elan 7/9/09 Letter at 2. This portion of the brief quotes the testimony of an Elan employee describing the fact that she did not always provide her superior with copies of promotional materials that she was submitting to the FDA. It is unclear how this information constitutes a trade secret that "gives [Elan] an opportunity to obtain an advantage over competitors . . . ." RESTATEMENT OF TORTS § 757 cmt. b at 5 (1939). Nor has Elan demonstrated that disclosure would result in a "clearly defined and serious injury." Allen, 420 F.Supp.2d at 302. Accordingly, this request for redaction is denied.

B. Skelaxin Business and Marketing Information

Elan's second and third categories of allegedly confidential information -- i.e., (2) confidential business information regarding the development of Skelaxin, and (3) non-public documents that include confidential business and marketing information regarding Skelaxin, see Elan 7/9/09 Letter at 2-3 -- both address business and marketing information regarding the development of Skelaxin, and thus are discussed together. Elan argues that its "confidential business information regarding the development of Skelaxin, as well as non-public Elan

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[12](…continued)
forwarded to the FDA hardly constitutes revelation of confidential business information.

documents that include confidential business and marketing information regarding Skelaxin®, all contain highly sensitive proprietary and trade secret information . . . ." Id. at 2. Elan then identifies the relevant portions of the briefs that contain allegedly confidential information.[13] See id. at 3. These portions describe Elan's decision to establish a Skelaxin Life Cycle Management team to address the threat of generic competition; that team's work and internal communications about delaying entry of a Skelaxin generic into the market; details regarding information used in staff training materials; and evidence as to what Elan knew about the half-life of Skelaxin, and when it knew it.

That these excerpts may "provide[] insight into [Elan's] internal decision-making does not explain how competitors can obtain economic value from this information." Forst, 639 F.Supp.2d at 957. Significantly, this allegedly confidential information is detailed in Judge Trager's decision denying Eon's fee application. See 9/28/10 M&O at 31-33. And while public disclosure of some of this information may cause Elan embarrassment, nothing in these portions of the briefs reflects any secret, proprietary information, the disclosure of which would result in any serious, cognizable injury. See, e.g., Nycomed, 2010 WL 889799, at *6 ("Although [defendant's] desire to shield this information from public view is understandable, '[c]ompetitive harm should not be taken to mean simply any injury to competitive position, as might flow from . . . embarrassing publicity'") (quoting Public Citizen Health Research Group

[13] To wit, Eon Brief at 2 (lines 12-16); Eon Brief at 3 (lines 1-24); Eon Brief at 4 n.7 (lines 1-2, 5-8); Eon Brief at 11 (lines 7-8, 12-16); Eon Brief at 14 (lines 4-8); Eon Brief at 15 (lines 1-10); Eon Brief at 34 (lines 4-11); King Brief at 14 (lines 20-29); King Brief at 23 (lines 24-[33]); King Brief at 24 (lines 1-9); Elan Brief at 8 (lines 6-16); Elan Brief at 9 (lines 19-28); Elan Brief at 31 (lines 14-17).

v. FDA, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983)); see Lugosch, 435 F.3d at 123 n.5 ("[T]he natural desire of parties to shield prejudicial information contained in judicial records from competitors and the public . . . cannot be accommodated by the courts without seriously undermining the tradition of an open judicial system.") (citation and internal quotation omitted); Forst, 639 F.Supp.2d at 957 ("If litigation documents are sealable simply because they can be used to portray a company in an unflattering way, the public would have access to precious few.").

In support of its argument that the aforesaid business and marketing information should remain confidential, Elan merely states, without support from any evidentiary submissions, that it

> has always maintained these proprietary and sensitive business and marketing documents in confidence and should not be forced to make them publicly available now. Further, if Elan's competitors were to gain access to such information, Elan's internal strategies regarding how it develops and markets its products could potentially be copied.

Elan 7/9/09 Letter at 3. Elan's conclusory assertions are precisely the kind of "broad allegations of harm unsubstantiated by specific examples or articulated reasoning [that thus] fail to satisfy the [Rule 26(c)] test" for good cause. In re Parmalat Secs. Litig., 258 F.R.D. at 244, 256 (denying protection of marketing strategies where party seeking protection failed to make a "specific showing of the economic value" of said marketing strategies); see also Salomon Smith Barney Inc. v. HBO & Co., No. 98CIV8721 (LAK), 2001 WL 225040, at *2 (S.D.N.Y. Mar. 7, 2001) (defendant failed to substantiate its request for continued confidential treatment, where its "argument reduces to the proposition that the documents should be

afforded confidential treatment because the documents at one time were not public. But the argument is circular and without merit."). In the absence of a showing of good cause under Rule 26(c), Elan has not demonstrated that its interest in maintaining confidentiality outweighs the strong presumption of public access to judicial documents. Accordingly, Elan's request to preclude public disclosure of the specified portions of the briefs is denied.

C. Research and Technical Information

Elan's final two categories of allegedly sensitive information -- i.e., (4) confidential research information regarding the development of Skelaxin, and (5) non-public documents that include confidential information of a technical nature regarding Skelaxin, see Elan 7/9/10 Letter at 3 -- both address information of a scientific nature regarding Skelaxin, and are therefore addressed together in this opinion.[14] Elan contends that the referenced portions reveal "scientific and technical information [that] is proprietary to Elan." Elan 7/9/09 Letter at 3.

The challenged excerpts describe Elan's decision to conduct a bioequivalence study; the results of that study; Elan's internal communications regarding a review of clinical studies that had already been conducted; and other evidence regarding Elan's awareness of prior research relating to metaxalone. No such excerpt reveals any non-public information of a scientific nature. The only technical information disclosed relates to findings that metaxalone is found in

[14] Within these categories, Elan seeks to redact the following: Eon Brief at 4 (lines 7-13); Eon Brief at 8 (lines 12-16); Eon Brief at 9 (lines 1-6); Eon Brief at 9 n.24; Eon Brief at 9 n.25; Eon Brief at 10 (lines 1-16); Eon Brief at 11 (lines 16-20); Eon Brief at 11 n.30 (lines 2-4); Eon Brief at 12 (lines 1-6); Eon Brief at 13-14 n.34; Elan Brief at 6 (lines 1-5); Elan Brief at 6 (lines 17-24); Elan Brief at 7 (lines 1-17); Elan Brief at 8 (lines 23-28); Elan Brief at 9 (lines 1-2); Elan Brief at 9 (lines 4-14); Elan Brief at 11 (lines 1-9).

greater concentrations in the blood of fed subjects -- a fact revealed in promotional materials for Skelaxin, and discussed in opinions issued by Judge Trager and the Federal Circuit. See Eon Brief at 12; King, 593 F.Supp.2d at 504; King, -- F.3d --, 2010 WL 3001333, at *2, *6; 9/28/10 M&O at 3, 17-19, 23-26, 27; see also Contratto, 227 F.R.D. at 312 (denying protection to a letter, the content of which "concerns publicly available information appearing in defendants' promotional materials"). Elan has again failed to demonstrate that these portions contain any secret, proprietary information, the disclosure of which would injure Elan competitively. See, e.g., id. ("Although the information . . . may be adverse to defendants' litigation position, it does not contain confidential, proprietary, or otherwise protectable information under Rule 26(c)."). Thus, Elan's request for continued sealing is denied.

II. Portions that King Seeks to Redact

King's argument in support of sealing its allegedly confidential information is predicated exclusively on the fact that the information "concerns material submitted to the [FDA] as part of the [NDA] for Ske[l]axin®." King 7/9/09 Letter at 1. However, as previously discussed, the mere fact that the information is imparted in communications with the FDA does not support a finding of good cause.

Moreover, none of the four referenced excerpts contains any information that even arguably can be characterized as a trade secret or confidential information. See King 7/9/09 Letter at 2. Two such excerpts concern the half-life of Skelaxin, see Eon Brief at 12 (lines 17-23); Eon Brief at 13 (lines 1-9) -- an issue disposed of earlier in this opinion.[15] Another

[15] See *supra* pp. 20-21.

excerpt concerns proposed advertisements that referred to prior art publications, see Eon Brief at 9 (lines 12-15), and the final portion concerns an unsuccessful effort to obtain FDA permission to include on the Skelaxin package insert a recommendation that metaxalone be ingested with food. See Eon Brief at 21 (lines 13-16). Given the nature of the aforesaid information, King understandably makes no attempt to substantiate the confidential nature of the redacted portions. Therefore, King's request for continued sealing is denied.

III. Third-Party Information

The final category of redactions implicates the privacy interests of an entity and individual who are not parties to this action: specifically, Mutual Pharmaceutical Corporation, Inc. and Dr. Kazem Fathie. Although the privacy interests of third parties can weigh heavily against public access, the nature and degree of any third-party injury in this case are far too insubstantial to overcome the presumption of public access to information contained in briefing by the parties. See generally Amodeo II, 71 F.3d at 1050-51.

In its letter to the Court, King alleges that Eon's brief discloses confidential information pertaining to Mutual. See King 7/9/09 Letter at 2 (citing Eon Brief at 4 n.7; Eon Brief at 15 (lines 1-10)).[16] Mutual's own letter to the Court does not, however, object to the disclosure of those portions,[17] but instead focuses on "the underlying documents referenced in the brief,

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[16] King's letter contains an apparent typographical error; instead of citing page 15 of Eon's brief, which discusses Mutual, King cites page 14, which does not. Compare King 7/9/09 Letter at 2 with Mutual 7/10/09 Letter at 1 (citing pages 4 and 15 of Eon's brief).

[17] Although, strictly speaking, Mutual's letter states that it does not object to disclosure of those portions of the brief *to Eon and Sandoz*, see Mutual 7/10/09 Letter at 1 (emphasis added), Mutual advances no argument to preclude unsealing and public access to the

(continued…)

which . . . do contain competitive business information related to our research and development, formulations and business plans." Mutual 7/10/09 Letter at 1-2. As the exhibits filed in connection with the briefing are not the subject of Judge Trager's orders regarding unsealing, see 6/25/09 M&O at 3; 1/14/10 Order, Mutual's concern falls outside the scope of the inquiry before this Court. Moreover, the references to Mutual in the Eon Brief do not disclose any information that is even arguably worthy of protection under Rule 26(c). See Eon Brief at 4 n.7; Eon Brief at 15 (lines 1-10).[18]

Another non-party whose allegedly confidential information is contained in briefing by a party is Dr. Kazem Fathie, one of the authors of articles that Eon alleged rendered the patents in suit obvious and thus invalid. See, e.g., Eon Brief at 7 n.13. Communicating to the Court through a letter from King, Dr. Fathie seeks continued confidential treatment for page 13 n.11 (lines 2-5) of the King Brief. See King 7/9/09 Letter at 2. According to King, Dr. Fathie informed King's counsel "that he understood the information disclosed in King's brief and during his deposition to be confidential under the protective order in this case . . . [and] asked counsel for King to relay to the Court his request that the information remain

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[17](…continued)
information contained therein.

[18] The first reference to Mutual in the Eon Brief states that after Elan initially resisted undertaking bioequivalence studies, Mutual, which was seeking to collaborate with Elan, encouraged Elan to conduct those studies and thereby effectively obtain another year of exclusivity on its Skelaxin product. See Eon Brief at 4 n.7. This information is disclosed in Judge Trager's opinion denying Eon fees, see 9/28/10 M&O at 32, and, in any event, is not protectable. Nor is the second reference to Mutual, see Eon Brief at 15 (lines 1-10), which summarizes the results of a Mutual metaxalone study concerning the half-life of metaxalone, which made findings consistent with those disclosed in Skelaxin promotional materials, among other places. See, e.g., Eon Brief at 12; *supra* pp. 20-21, 25-26.

confidential." Id.[19] However, Dr. Fathie's reliance on a stipulated confidentiality order that on its face was limited and temporary does not justify sealing portions of judicial records.[20]

In any event, nothing worthy of protection is disclosed in the footnote in question, which recounts that during his deposition, Dr. Fathie could not recall a single instance wherein a patient had "ever taken metaxalone with food, or complained of having an upset stomach as a result of taking metaxalone." King Brief at 13 n.11 (lines 2-5). As neither King nor Dr. Fathie have identified any cognizable injury that Dr. Fathie would suffer as a result of this disclosure, the request to redact the footnote is denied.

Equally makeweight is the claim -- again communicated through correspondence from King -- that the allegedly confidential information of non-parties Rite Aid Pharmacy and First Data Bank should be redacted from page 21 (lines 5-12) of the Eon Brief. See King 7/9/09 Letter at 3. As an initial matter, despite their awareness of Judge Trager's deadline for objecting to disclosure, neither entity filed objections or requested that any party do so on its behalf. See id. Since the lines in question concern the public distribution of published drug monographs, see Eon Brief at 21 (lines 5-12), the non-parties' failure to object to unsealing is not surprising. Accordingly, the information is not confidential and should not be redacted from the brief.

CONCLUSION

For the foregoing reasons, this Court orders that the four briefs submitted in support of

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[19] King's letter to the Court attaches an email from a "Ramin Fathie" (with a copy to Kazem Fathie), conveying this request. See King 7/9/09 Letter Ex. A.

[20] See *supra* pp. 6-7.

and in opposition to Eon's Motion for Determination of Exceptional Case be unsealed in their entirety.

Any objections to any portion of this Memorandum and Order must be filed with the Honorable Judge David G. Trager on or before October 15, 2010. Failure to file objections in a timely manner may waive a right to appeal the District Court order.

The Clerk is directed to enter this Opinion into the ECF system and to mail a copy to Mutual in care of its counsel:

Andrew M. Berdon, Esq.
Quinn Emanuel
51 Madison Ave., 22nd Floor
New York, NY 10010

SO ORDERED.

Dated: Brooklyn, New York
September 28, 2010

ROANNE L. MANN
UNITED STATES MAGISTRATE JUDGE